

AI
cont'd
Duffy

conducting mass spectrophotometric analysis on said sample;
evidencing and categorizing at least one biopolymer marker
sequence or analyte thereof isolated from said sample; and,
comparing said at least one isolated biopolymer marker
sequence or analyte thereof to the biopolymer marker sequence as
set forth in claim 1;

wherein correlation of said isolated biopolymer marker and
said biopolymer marker sequence as set forth in claim 1 evidences
and categorizes said at least one disease state.

4. (New) The method of claim 3, wherein said step of evidencing
and categorizing is (particularly) directed to biopolymer markers or
analytes thereof linked to at least one risk of disease development
of said patient.

5. (New) The method of claim 3, wherein said step of evidencing
and categorizing is (particularly) directed to biopolymer markers or
analytes thereof related to the existence of a particular disease
state.

6. (New) The method of claim 3, wherein the sample is an
unfractionated body fluid or a tissue sample.

Al
out'l
Lubbe

7. (New) The method of claim 3, wherein said sample is ~~at least~~
~~selected from~~
~~one of~~ the group consisting of blood, blood products, urine,
saliva, cerebrospinal fluid, and lymph.

8. (New) The method of claim 3, wherein said mass
spectrophotometric analysis is Surface Enhanced Laser Desorption
Ionization (SELDI) mass spectrometry (MS).

9. (New) The method of claim 3, wherein said patient is a human.

10. (New) A diagnostic assay kit for determining the presence of
the biopolymer marker or analyte thereof of claim 1 comprising:

at least one biochemical material which is capable of
specifically binding with a biomolecule which includes at least
said biopolymer marker or analyte thereof, and

means for determining binding between said biochemical
material and said biomolecule.

11. (New) The diagnostic assay kit of claim 10, wherein said
biochemical material or biomolecule is immobilized on a solid
support.

12. (New) The diagnostic assay kit of claim 10 including:
at least one labeled biochemical material.

AI
cont'd
Sub 107

13. (New) The diagnostic assay kit of claim 10, wherein said biochemical material is an antibody.

14. (New) The diagnostic assay kit of claim 12, wherein said labeled biochemical material is an antibody.

15. (New) The diagnostic assay kit of claim 10, wherein the sample is an unfractionated body fluid or a tissue sample.

16. (New) The diagnostic assay kit of claim 10, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

17. (New) The diagnostic assay kit of claim 10, wherein said marker includes the sequence ID SKITHRIHWESASLL and said biochemical material is at least one monoclonal antibody specific therefore.

18. (New) A kit for diagnosing, determining risk-assessment, and identifying therapeutic avenues related to a disease state comprising:

at least one biochemical material which is capable of specifically binding with a biomolecule which includes at least one biopolymer marker including the sequence ID SKITHRIHWESASLL or an analyte thereof related to said disease state; and

↓ SEQ ID
No. 1

AI
cont'd
Sub B67

means for determining binding between said biochemical material and said biomolecule;

whereby at least one analysis to determine a presence of a marker, analyte thereof, or a biochemical material specific thereto, is carried out on a sample.

19. (New) The kit of claim **18**, wherein said biochemical material or biomolecule is immobilized on a solid support.

20. (New) The kit of claim **18** including:
at least one labeled biochemical material.

21. (New) The kit of claim **18**, wherein said biochemical material is an antibody.

22. (New) The kit of claim **20**, wherein said labeled biochemical material is an antibody.

23. (New) The kit of claim **18**, wherein the sample is an unfractionated body fluid or a tissue sample.

24. (New) The kit of claim **18**, wherein said sample is at least one of the group consisting of blood, blood products, urine, saliva, cerebrospinal fluid, and lymph.

AI
cont'd
Sub B

25. (New) The kit of claim 18, wherein said marker includes the sequence ID SKITHRIHWESASLL or at least one analyte thereof and said biochemical material is at least one monoclonal antibody specific therefore. *SEQ ID NO: 1*

26. (New) The kit of claim 18, wherein said diagnosing, determining risk assessment, and identifying therapeutic avenues is carried out on a single sample.

27. (New) The kit of claim 18, wherein said diagnosing, determining risk assessment, and identifying therapeutic avenues is carried out on multiple samples such that at least one analysis is carried out on a first sample and at least another analysis is carried out on a second sample.

28. (New) The kit of claim 27, wherein said first and second samples are obtained at different time periods.

29. (New) Polyclonal antibodies produced against the marker sequence ID SKITHRIHWESASLL in at least one animal host.

30. (New) An antibody that specifically binds a biopolymer including the marker sequence ID SKITHRIHWESASLL or at least one analyte thereof.

AI
antib
Subbio

31. (New) The antibody of claim 30 that is a monoclonal antibody.

32. (New) The antibody of claim 30 that is a polyclonal antibody.

33. (New) A process for identifying therapeutic avenues related to a disease state comprising:

conducting an analysis as provided by the kit of claim 18; and

interacting with a biopolymer including the sequence ID SKITHRIHWESASLL or at least one analyte thereof;

whereby therapeutic avenues are developed.

34. (New) The process for identifying therapeutic avenues related to a disease state in accordance with claim 33, wherein said therapeutic avenues regulate the presence or absence of the biopolymer including the sequence ID SKITHRIHWESASLL or at least one analyte thereof.

35. (New) A process for regulating a disease state by controlling the presence or absence of a biopolymer including the sequence ID SKITHRIHWESASLL or at least one analyte thereof.

SEQ ID NO: